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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,912	FOLLONIER ET AL.	
	Examiner	Art Unit	
	DAVID J. VENCI	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 25, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 55-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33 and 55-62* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *February 25, 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply filed February 25, 2008. Claims 61 and 62 are newly added, and claims 34-39, 41-47 and 49-53 are cancelled.

Claims 1-33 and 55-62 are pending and under examination.

Claim Objections

Claim 13 is objected to because of the following informality:

> In element d), the phrase "and at least one light detecting element wherein; the light emitted by the at least one light emitting element is transmitted into the fluid in the inner volume of said at least one tube by at least one primary light connecting element;" appears grammatically awkward. It is not clear what objects are members of element d).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 16-21, 24-33 and 55-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (US 6,020,207).

Liu describes a system (see Title, "Sensors") comprising:

a. a light-emitting element emitting light (see Fig. 4, light source 30);

b. two light-connecting elements transmitting light (see *e.g.*, Fig. 3, solid optical fiber 18, solid optical fiber 20; see *also*, Fig. 4, mirror 32, lens 34; optical fiber 36); and a light detecting element (see Fig. 4, light detector 38, photodiode array 40) wherein;

c. a measuring cell tube (see *e.g.*, Fig. 1, sensor cell 10; see *also*, protective outer cover 22; see *also*, amorphous polymer material 14; see *also*, tube 12) having a first opening and second opening (see *e.g.*, Fig. 3, "↑", "↓", solid optical fiber 18, solid optical fiber 20; see *also*, col. 3, line 17, "proximal and distal ends of tube 12"), the measuring cell tube comprising:

    1. an inner surface (see *e.g.*, Fig. 1, interior wall surface 26; see *also*, tube 12) coated with a binding agent (see Fig. 1, sensing molecules 24), the binding agent binding a target (see Fig. 2, analyte molecules 28);

    2. a fluid in the inner volume of said tube, and optically coupled to the light-connecting elements, the fluid comprising light (see Fig. 3, the zig-zag arrows).

Claims 1-6, 9, 11-19, 21, 24-28, 30, 32, 33, 55-58 and 60-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohnenkamp (US 6,252,657).

Bohnenkamp describes a system (see Title, "Fluorometer") comprising:

a. a light-emitting element emitting light (see Fig. 1, light source 2);

b. two light-connecting elements transmitting light (see Fig. 1, optical wedge 6, optical filters 5); and a light detecting element (see Fig. 1, light sensitive instrument 4) wherein;

c. a measuring cell tube (see Fig. 1, capillary 1) having a first opening and second opening (see *e.g.*, col. 3, line 61, "front end"; see *also*, col. 4, lines 8-9, "conical end"), the measuring cell tube comprising:

    1. an inner surface (see col. 1, line 51, "inner wall of that capillary") coated with a binding agent (see *e.g.*, col. 3, line 9, "avidin coated capillaries"), the binding agent binding a target (see *e.g.*, col. 3, line 10, "biotin covered microbeads");

    2. a fluid in the inner volume of said tube (see *e.g.*, col. 3, line 6, "the sample"; see *also*, col. 3, lines 56-57, "The capillary[…] contains in the inner volume at least one analyte") (paraphrasing mine)), and optically coupled to the light-connecting elements (see *e.g.*, Fig. 1, optical wedge 6), the fluid comprising light (see Abstract, second sentence, "part of the light penetrates the capillary").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14, 16-33 and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilby & Carson (US 5,184,192) in view of Liu (US 6,020,207).

Gilby & Carson describe a system (see Title, "Photometric apparatus with a flow cell") comprising:

a. a light-emitting element emitting light (see Fig. 1, light source 20);

b. two light-connecting elements transmitting light (see *e.g.*, Fig. 1, input optical fiber 22; see *also*, Fig. 1, exit optical fiber 28; see *also*, col. 4, line 40, "optical filters"); and a light detecting element (see Fig. 1, detector 30) wherein;

c. a measuring cell tube (see *e.g.*, Fig. 2, cell body 32; see *also*, Fig. 1, flow cell 10; see *also*, Fig. 1, bore 24; see *also*, col. 3, line 24, "tubular conduit") having a first opening and second opening (see *e.g.*, Fig. 1, exit 16; fluid outlet section 18; see *also*, Fig. 1, input optical fiber 22; see *also*, Fig. 1, exit optical fiber 28; see *also*, col. 3, lines 48-49, "ends of the conduit"; line 49, "flow ports"), the measuring cell tube comprising:

1. an inner surface (see *e.g.*, Fig. 1, bore 24; see *also*, Fig. 2, fluoropolymer layer 12; see *also*, col. 3, lines 23-24, "inner surface") coated with a binding agent (see), the binding agent binding a target (see);

2. a fluid in the inner volume of said tube, and optically coupled to the light-connecting elements, the fluid comprising light (see Fig. 2, liquid 26; see *also*, col. 4, lines 51-52, "light is guided by total internal reflection at the boundary between liquid 26 and layer 12").

Gilby & Carson do not describe a binding agent.

However, Liu describes binding agents (see Fig. 1, sensing molecules 24) for binding target analytes (see Fig. 2, analyte molecules 28) from a sample.

It would have been obvious to a person of ordinary skill to include Liu's binding agents with Gilby's & Carson's system because Liu said binding agents improve assay selectivity (see *e.g.*, col. 4, lines 4-5, "selectively attracts"; see *also*, col. 7, lines 51-56).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 and 55-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-30 and 32-35 of copending Application No. 10/572931 in view of Hawes (US 3,556,659).

Application No. 10/572931 claims a system (see claim 14) using language almost identical to independent claims 1 and 13 of the instant application.

Application No. 10/572931 does not claim a fluid (contained within the measuring cell) comprising light.

However, Hawes describes such a fluid contained within a measuring cell, the fluid comprising light (see col. 3, lines 37-42).

It would have been obvious to a person of ordinary skill to claim Hawes' fluid in Application No. 10/572931 because Hawes discovered that such a sensor configuration "minimizes fluorescence of the glass wall and scattering of light from the cell itself" (see col. 3, lines 27-36), thereby improving the glass wall configuration claimed in Application No. 10/572931.

Response to Arguments

Liu (US 6,020,207)

In prior Office Action, claims 1-14, 16-18, 20, 21, 24-33 and 55-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Liu (US 6,020,207).

In response, Applicants appear to argue Liu does not describe the claimed measuring cell because the refractive index of the tube is too high relative to the inner fluid and outer coating.

Applicants' argument has been carefully considered but is not persuasive. The scope of Applicants' argument, based upon unidentified materials having certain differential refractive indices, does not appear commensurate to the scope of the claimed invention.

Even assuming Applicants' above paraphrased assertion is correct, as claimed, Applicants' invention merely requires a fluid within a tube, which is optically coupled to light-connecting elements and comprises light. Similarly, Liu describes such a device in Figure 3, which appears to depict a fluid comprising light (see Fig. 3, the zig-zag arrows) and is optically coupled to two light-connecting elements (see *e.g.*, Fig. 3, solid optical fiber 18, solid optical fiber 20; see *also*, Fig. 4, mirror 32, lens 34; optical fiber 36).

Examiner's interpretation of the zig-zag arrows in Figure 3 as representing "light" appears consistent with the name of Liu's devices, *i.e.*, "*liquid waveguide* capillary cell" ("LWCC"), and appears consistent with Liu's ultimate goal of detecting optical signals originating from *fluid* analytes (as opposed to hypothetical "tube" analytes).

Bohnenkamp (US 6,252,657)

In prior Office Action, claims 1-6, 9, 11-18, 21, 24-28, 30, 32, 33, 55-58, 60 were rejected under 35 U.S.C. 102(b) as being anticipated by Bohnenkamp (US 6,252,657).

In response, Applicants appear to argue Bohnenkamp does not describe the claimed measuring cell because Bohnenkamp describes a tube having an inner coating with a low-refractive index relative to the higher refractive index of the surrounding tube material (see Applicants' reply, p. 16, first paragraph, *citing* Bohnenkamp abstract).

Applicants' argument has been carefully considered but is not persuasive. The scope of Applicants' argument, based upon unidentified materials having certain differential refractive indices, does not appear commensurate to the scope of the claimed invention.

Even assuming Applicants' above paraphrased assertion is correct, as claimed, Applicants' invention merely requires a fluid within a tube, which is optically coupled to light-connecting elements and comprises light. Similarly, Bohnenkamp describes such a device in Figure 1, which appears to depict a fluid comprising light (see Abstract, second sentence, "part of the light penetrates the capillary") and is optically coupled to two light-connecting elements (see Fig. 1, optical wedge 6, optical filters 5). Furthermore, Bohnenkamp describes a device configuration where light penetrates the capillary at an angle approximately normal to the surface of the capillary (*i.e.*, $\theta << \theta_{\text{critical angle}}$) where one would not expect any refraction.

Examiner's proposed optical mechanism of the device in Figure 1 appears consistent with Bohnenkamp's disclosure that "part of the light penetrates the capillary" (see Abstract, second sentence), and appears consistent with Bohnenkamp's ultimate goal of detecting optical signals originating from *fluid* analytes (as opposed to hypothetical "tube" analytes).

Gilby & Carson (US 5,184,192) in view of Liu (US 6,020,207)

In prior Office Action, claims 1-14, 16-33 and 55-60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gilby & Carson (US 5,184,192) in view of Liu (US 6,020,207).

In response, Applicants argue that a combination of Liu's binding agents could be detrimental to Gilby's & Carson's device, which requires a fluoropolymer coating.

Applicants' argument has been carefully considered but is not persuasive. Examiner acknowledges that Carson's device requires a fluoropolymer coating. However, it is not clear from Applicants' argument, or from the teachings of Gilby & Carson and Liu, how/why Liu's binding agents could be detrimental to Gilby's & Carson's device, or its fluoropolymer coating.

Both Gilby's & Carson's and Liu's devices incorporate fluoropolymer coatings, in part, because Gilby's & Carson's fluoropolymer coating represented an improvement in *detection sensitivity* over prior art capillary waveguides (see Gilby & Carson, col. 1, lines 58-61). Along this same vein of improvements in *detection sensitivity*, Liu describes binding agents for binding target analytes (see Fig. 1, sensing molecules 24; see *also*, Fig. 2, analyte molecules 28), which according to Liu, improves assay selectivity (see *e.g.*, col. 4, lines 4-5, "selectively attracts"; see *also*, col. 7, lines 51-56).

How Liu's binding agents are "detrimental" is not clear, considering that both Gilby's & Carson's and Liu's devices incorporate fluoropolymer coatings, and both Gilby & Carson and Liu are concerned with improving detection sensitivity. The test for obviousness is what the *combined* teachings of Gilby & Carson and Liu suggest to persons of ordinary skill. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Venci whose telephone number is (571)272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641